IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9112

Bartle, J. July 11, 2013

Debbie Gordon ("Ms. Gordon" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether Ms. Gordon has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether she met her burden of proving that her claim

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Lee Gordon, Ms. Gordon's spouse, also has submitted a derivative claim for benefits.

was not based, in whole or in part, on any intentional material misrepresentation of fact.[3]

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In January, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, W. Marcus Brann, M.D., F.A.C.C., F.A.C.P. Dr. Brann is no stranger to this litigation. According to the Trust, he has signed at least 765 Green Forms on behalf of claimants seeking Matrix Benefits.

---

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Based on an echocardiogram dated November 7, 2002, Dr. Brann attested in Part II of Ms. Gordon's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $578,687.[5]

In the report of claimant's echocardiogram, Dr. Brann stated that Ms. Gordon had moderate mitral regurgitation of 25%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Brann also stated that "[t]here is mild left atrial enlargement" and noted that the left atrium measured 60 mm in the supero-inferior dimension and 41 mm in the antero-posterior dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater

---

4. Dr. Brann also attested that claimant suffered from mild aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors needed for a Level II claim.

than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii).

In November, 2005, the Trust forwarded the claim for review by Maged M. Rizk, M.D., Ph.D., F.A.C.C., one of its auditing cardiologists. Dr. Rizk accepted Dr. Brann's findings of moderate mitral regurgitation and an enlarged left atrial dimension. Pursuant to Court Approved Procedure ("CAP") No. 11, the Consensus Expert Panel subsequently reviewed Ms. Gordon's claim and determined the claim should be re-audited because the "[d]egree of [mitral regurgitation] appears less than moderate."[6] In June, 2006, the Trust informed Ms. Gordon that it had accepted the Consensus Expert Panel's recommendation that her claim be re-audited.

In July, 2006, the Trust forwarded the claim for review by another auditing cardiologist, Craig M. Oliner, M.D. Dr. Oliner also concluded that there was a reasonable medical basis for Dr. Brann's findings that claimant had moderate mitral regurgitation and an abnormal left atrial dimension. With respect to the level of Ms. Gordon's mitral regurgitation, Dr. Oliner observed, "Although the RJA's are overtraced and include non-[mitral regurgitant] signal and the LAA is undertraced by not including the whole [left atrium], the

---

6. The Consensus Expert Panel consists of three cardiologists, one designated by each of Class Counsel, the Trust, and Wyeth. See Pretrial Order ("PTO") No. 6100 (Mar. 31, 2005). We approved creation of the Consensus Expert Panel to "monitor the performance of the Auditing Cardiologists and to develop procedures for quality assurance in the Audit of Claims for Matrix Compensation Benefits." Id.

estimated RJA/LAA is aprroximately [sic] 20%." With respect to her left atrial dimension, Dr. Oliner measured Ms. Gordon's left atrial dimension in the supero-inferior dimension to be 59 mm.

Pursuant to Rule 5 of the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Trust undertook "to determine whether there were any intentional material misrepresentations made in connection with the Claim." As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of echocardiogram system use during the performance of echocardiographic studies and the resulting interpretations submitted in support of certain claims. As stated in his January 26, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

> In Ms. Gordon's study, the use of high color gain, high image gain, color persistence, decreased low velocity reject, decreased velocity scale (PRF and Nyquist), and color pixels dominant over anatomy, the selection and planimetry of backflow, and the overmeasurement of the mitral "jet," as well as the undermeasurement of the left atrial area are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated or created the appearance of regurgitation or jet duration.

Thus, notwithstanding Dr. Oliner's findings at audit, the Trust issued a post-audit determination denying Ms. Gordon's claim based on its conclusion that there was substantial evidence of intentional material misrepresentation of fact in connection with the claim. Pursuant to the Audit Rules, Ms. Gordon

contested this adverse determination.[7] In contest, claimant noted that she did not dispute the findings of the Trust's two auditing cardiologists who determined there was a reasonable medical basis for her claim. She also attached a September 8, 2005 letter from Class Counsel to the Trust[8] and a motion filed on claimant's behalf to enforce the Settlement Agreement.[9]

The Trust then issued a final post-audit determination, again denying Ms. Gordon's claim. The Trust asserted that Ms. Gordon's contest did not comply with Audit Rule 18(b) because "[i]t does not state the factual reasons for [her] Contest, nor

---

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Gordon's claim.

8. In this letter, Class Counsel argued, among other things, that the Trust could not deny payment on any claim in which a post-audit determination letter had been sent unless it found that the claim was based on a fraudulent echocardiogram and that the Trust could not rely on the reports of Dr. Kisslo to determine whether a claim in which a post-audit determination letter had been sent was fraudulent. The issues raised in Class Counsel's letter also were the subject of a motion filed by Class Counsel and joined by a number of firms representing various Class Members. Class Counsel and all but one firm subsequently withdrew the motion after the adoption of certain Court Approved Procedures. We denied the motion of the remaining firm following briefing and argument. See PTO No. 6099 (Mar. 31, 2006).

9. In her motion, Ms. Gordon argues that she should be paid because her claim passed audit under Court Approved Procedure No. 11 and the Trust therefore was not permitted to submit the claim for review by Dr. Kisslo. Ms. Gordon also argues that the Trust's allegation of intentional material misrepresentations of fact fails because the Trust cannot establish, as to her conduct, each of the elements of intentional misrepresentation under Pennsylvania law.

does it identify any alleged errors made by Dr. Kisslo in his Declaration." The Trust further noted that the contest "does not include a verified statement of a medical expert, nor any other evidence relating to the specific issues present in [Ms. Gordon's] claim." The Trust, using Dr. Kisslo's findings for support, also reasserted its allegation that Ms. Gordon's claim contained substantial evidence of intentional material misrepresentations.

Ms. Gordon disputed the Trust's final determination and requested that her claim proceed through the show cause process as established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Gordon's claim should be paid. On June 12, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7253 (June 12, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, incorporating by reference the materials she submitted in contest. The Trust did not reply. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the (continued...)

the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Where the Trust's Post-Audit Determination finds intentional misrepresentation of fact, the claimant has the burden of proving that all representations of material fact in connection with her claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers and no intentional material misrepresentation of fact

---

10. (...continued)
jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

> There was excessive two dimensional echo gain with distortion of cardiac structures. There was excessive color gain causing artifact within the tissue. The pulse repetition frequency [PRF] was decreased from 4,000 Hz to 3,500 Hz with the Nyquist limit decreased from 70 to 61 during the time that the mitral regurgitation jet was being evaluated in the apical four chamber view. There was no imaging issue that would cause the sonographer to change these settings. In addition, it was noted that the low velocity reject setting was 2.6 cm per second.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part, that:

> Some degree of mitral regurgitation was noted in the parasternal long axis view. There was a small jet of mitral regurgitation noted in the apical two chamber view when the PRF was 4,000 Hz. The RJA/LAA ratio was less than 12% in this view. The mitral regurgitation jet appeared most impressive in the apical four chamber view. This was a laterally directed jet into the left atrium. There was significant color artifact in the evaluation of the mitral regurgitation jet. However, in mid systole, I was able to accurately planimeter the RJA. The RJA was no larger

> than 3.5 cm2 in those cardiac cycles in which the mitral regurgitation appeared most impressive. There were several supposed regurgitant jet areas measured by the sonographer. These measurements were 5.29 cm2, 5.06 cm2, and 5.37 cm2. These supposed RJA's are inaccurate. These measurements all occurred at the very beginning of systole and included backflow as well as tracings of flow on the left ventricular side of the mitral valve. In addition, these planimetered areas included non-mitral regurgitation low velocity flow. The correct RJA planimetered areas were no greater than 3.5 cm2. These RJA's were sustained and representative of mitral regurgitation in real time. I was able to accurately measure the LAA in the apical four chamber view and found this measurement to be 22.1 cm2. The sonographer measurement of the supposed LAA was 20.27 cm2. This measurement was inaccurately small as part of the posterior left atrium was not included in this measurement. Therefore, the RJA/LAA ratio was less than 16% in those cardiac cycles in which the mitral regurgitation appeared most severe. The majority of cardiac cycles demonstrated RJA/LAA ratios much less than 16%.

After reviewing the entire Show Cause Record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of those two documents, we have previously explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole;

(4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Kisslo and Dr. Vigilante each found that claimant's sonographer improperly selected, traced, and measured a supposed regurgitant "jet" that consisted of backflow rather than true high velocity sustained regurgitant flow. In addition, they determined that the sonographer underestimated claimant's LAA, which artificially increased the level of Ms. Gordon's regurgitation. Finally, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included clear evidence of excessive image gain, excessive color gain, decreased velocity scale and PRF, and decreased low velocity reject.

Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that Ms. Gordon's echocardiogram demonstrated only mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's opinion

that Ms. Gordon had moderate mitral regurgitation.[11] Specifically, he explained that "the RJA/LAA ratio was less than 16% in those cardiac cycles in which the mitral regurgitation appeared most severe" and that "[t]he majority of cardiac cycles demonstrated RJA/LAA ratios much less than 16%."

Claimant does not substantively challenge the specific findings of Dr. Kisslo and Dr. Vigilante regarding the manner in which her echocardiogram was conducted or her level of mitral regurgitation was evaluated. Rather, claimant refers to documents that contend Dr. Kisslo lacked the requisite independence to validate his findings. Notably, Ms. Gordon makes no such contention against Dr. Vigilante, an independent cardiologist appointed by the court who reached similar conclusions during a separate review. Without identifying some specific error by the Trust's expert and the Technical Advisor, claimant cannot meet her burden of proof in establishing that her claim is payable.

We also reject claimant's argument that she should be paid because her claim passed a second audit pursuant to CAP No. 11 and the Trust therefore was not permitted to submit the claim for review by Dr. Kisslo. As an initial matter, this argument is belied by the express terms of CAP No. 11, which permit the Trust to deny a claim for an intentional

---

11. Despite an opportunity to do so, Ms. Gordon did not submit a response to the Technical Advisor Report. See Audit Rule 34.

misrepresentation of fact after re-audit. Specifically, CAP No. 11 states, in pertinent part, that:

> If after the Audit or re-Audit of a Claim for Matrix Compensation Benefits, the Trust intends to issue a Post-Audit Determination denying such claim on the ground that the Class Member intentionally made a material misrepresentation of fact in connection with the Claim ....

See CAP No. 11 ¶ 10. This argument also ignores the plain language of the Audit Rules, which provides that the Trust must conduct a review separate from the auditing cardiologist with respect to intentional material misrepresentations. Specifically, the Audit Rules state, in pertinent part, that:

> The Auditing Cardiologist shall review a Claim in accordance with these Rules to determine whether there was a reasonable medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue ("GREEN Form Question at Issue"). The Trust shall review a Claim to determine whether there were any intentional material misrepresentations made in connection with the Claim. The Trust may consider information from other Claims in Audit to determine the existence of facts or a pattern of misrepresentations implicating intentional misconduct by an attorney and/or physician that may warrant relief pursuant to Section VI.E.8 of the Settlement Agreement.

Audit Rule 5. Based on the findings of Dr. Kisslo, the Trust denied Ms. Gordon's claim, determining that the claim was based on one or more intentional material misrepresentations of fact.

Ms. Gordon disputed this determination and proceeded to the show cause process. We need not determine whether there was, in fact, any intentional material misrepresentation of fact in

connection with Ms. Gordon's claim given our conclusion, based on our review of the entire record, that there is no reasonable medical basis for Dr. Brann's representation that claimant had moderate mitral regurgitation.[12]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Gordon's claim for Matrix Benefits and the related derivative claim submitted by her spouse.[13]

---

12. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625 at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has passed audit.

13. Accordingly, we also will deny claimant's motion to enforce.